UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ZONGXUAN JIN, KOICHIRO MURAMATSU, HIDEYUKI YAMADA NAOZUMI FUWA and HIROSHIGE HIBASAMI

Appeal No. 2005-2589
Application No. 09/863,316

ON BRIEF

Before SCHEINER, ADAMS and GREEN, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 5-12, the only claims remaining in the application.

BACKGROUND

"Chemoprophylaxis of cancer involves primary prevention of . . . the initiation and promotion of cancer by application of chemical substances." Specification, page 1. The present invention is directed to a method of inhibiting skin cancer in a mammal, using "a naturally-occurring preventive agent for skin cancer having sericin (including hydrolysis products of sericin) [as] its active ingredient" (id., page 2), which "can be [administered] orally, . . . [and] can also be used as a skin external preparation" (id., page 4). Sericin, extracted "from the cocoon or raw silk expelled by silkworms" (id., page 3), "is highly hydrophilic, dissolves easily in cold water, has good miscibility with other drugs, and its aqueous solutions do not form gel[s], have low viscosity and can be handled easily" (id., page 4).

According to the specification, "research on chemoprophylaxis using animals is conducted using chemical carcinogenesis models" (Specification, page 1). "[C]arcinogenesis is a two-stage process consisting of initiation and promotion[,] [t]hus, chemoprophylactic agents . . . consist of those that inhibit . . . the initiation stage of an animal chemical carcinogenesis model, and those [that] inhibit . . . the promotion stage" (id., pages 1-2). The specification provides a working example in which "[t]he time-dependent inhibitory action [of serecin] on skin carcinogenesis in mice . . . was investigated" (id., page 6). Briefly, mice were divided into three groups – a control group, test group A and test group B. The skin carcinogenesis initiator, 7,12-dimethylbenzen[α]anthracene (DMBA) was applied to the shaved backs of the mice in all three groups; beginning two weeks later, the carcinogenesis promoter, 12-*O*-tetradecanoyl-phorbol-13-acetate (TPA), was applied to the same sites, three times a week for 20 weeks. In addition, sericin was applied to the backs of the mice in test groups A and B every time TPA was applied (a 2.5 % solution of a sericin hydrolysate for test group A, and a 5 % solution for test group B). The development of skin papilloma was inhibited, in a dose dependent manner, in those mice that received topical sericin. Id., pages 6-7.

THE CLAIMS

Claims 9, 10 and 12 are representative of the subject matter on appeal:

9. A method of inhibiting skin cancer in a mammal, comprising the step of administering to the mammal in need of treatment for inhibition of skin cancer a composition comprised of a hydrolysis product of sericin.

10. The method of claim 9, wherein the weight average molecular weight of said hydrolysis product of sericin is from 5,000 to 100,000.

12. The method of claim 10, where said administering step is comprised of administering the composition by a means selected from the group consisting of oral, intraperitoneal, intravenous, and topical means.

DISCUSSION

The examiner rejected all of the pending claims under 35 U.S.C. § 112, first paragraph, as lacking enablement, and also under 35 U.S.C. § 103, as unpatentable over Yamada.[1]

We reverse the rejection of claims 5-12 under 35 U.S.C. § 112, first paragraph, but affirm the rejection of claims 5-12 under 35 U.S.C. § 103.

Enablement

The examiner rejected claims 5-12 under the first paragraph of 35 U.S.C. § 112, because the specification is "enabling for inhibition of [DMBA- and TPA- induced] skin cancer in a mouse with a shaved back[,]" but "does not reasonably provide enablement for inhibit[ion of] skin cancer" broadly. Answer, page 3. The examiner considered the factors set out in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), and concluded that "it would require undue, unpredictable experimentation to . . . inhibit the development of [non-DMBA and -TPA induced] skin cancer in a mammal by the administration of sericin" (id., page 6) principally because skin cancer has "many different causes such as heredity . . . , environment such as UV exposure, multiple nevi or atypical moles, exposure to coal and arsenic compounds, . . . repeated exposure to X-rays, and scars from disease and burns" which "may or may not be addressed by the administration [of] sericin" (id., page 4). If we understand the examiner's concern, it is that the claims encompass prevention of skin cancers in general, but the administration of sericin to prevent skin cancers arising from anything other than DMBA/TPA induction is "likely" to be "unsuccessful . . . given the lack of significant guidance from the specification of [sic] prior art regarding inhibition of skin cancer in general" (id., page 6).

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[1] Yamada et al., U.S. Patent 6,165,982, filed November 6, 1997, issued December 26, 2000.

The examiner bears the initial burden of showing that a claimed invention is nonenabled. See In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) ("[T]he PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by [a] claim is not adequately enabled by the description of the invention provided in the specification of the application."). "[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" Id. at 1561, 27 USPQ2d at 1513. "That some experimentation may be required is not fatal; the issue is whether the amount of experimentation required is 'undue.'" In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).

We agree with appellants that the examiner has not adequately shown that undue experimentation would have been required to practice the claimed method. First, we do not agree with the examiner's conclusion that the mere lack of evidence regarding inhibition of non-DMBA/TPA-induced skin cancers with sericin means that treatment of these cancers is "likely" to be "unsuccessful." Second, even if administering sericin prophylactically does not prevent all skin cancers, enabling the full scope of a claim does not necessarily require enabling every embodiment within the claim. See, e.g., Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 414 (Fed. Cir. 1984): "Even if some of the claimed combinations [are] inoperative, the claims are not necessarily invalid . . . Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid." Atlas Powder concerned claims to a product, not a method as

here, but the same principle applies – a claimed method does not lack enablement merely because it cannot be practiced under some circumstances or it does not always achieve some particular result.

In re Cortright, 165 F.3d 1353, 49 USPQ2d 1464 (Fed. Cir. 1999) is instructive. In Cortright, the applicant claimed a method of "treating scalp baldness with an antimicrobial to restore hair growth." Id. at 1355, 49 USPQ2d at 1465. The board reversed a rejection for lack of utility, but entered a new rejection for lack of enablement, on the basis that "restor[ing] hair growth" required returning the user's hair to its original state (a full head of hair). See id. "Because Cortright's written description discloses results of only 'three times as much hair growth as two months earlier,' 'filling-in some,' and 'fuzz,' the board reasoned, it does not support the breadth of the claims." Id. at 1358, 49 USPQ2d at 1467.

The court disagreed with the board's claim interpretation, holding that "one of ordinary skill would construe this phrase [restoring hair growth] as meaning that the claimed method increases the amount of hair grown on the scalp but does not necessarily produce a full head of hair." Id. at 1359, 49 USPQ2d at 1468. The court concluded that the claims, so construed, were enabled. Id.

As with the present claims, the claims in Cortright encompassed a method of obtaining results that might be difficult to achieve: in Cortright, complete restoration of hair growth; here, prevention of skin cancer generically, no matter its cause. However, as in Cortright, the present claims do not require that particular result: the present claims require only inhibition of some skin cancers; Cortright's claims required only restoration of some hair growth.

The court in Cortright did not dispute the board's conclusion that completely restoring hair growth by applying an antimicrobial would require undue experimentation. See id. At 1357, 49 USPQ2d at 1467. The court nonetheless concluded that the claimed method did not lack enablement merely because it encompassed a difficult-to-achieve outcome. The same reasoning applies here. The examiner may be correct that preventing all skin cancers by applying sericin prophylactically may require undue experimentation, and ultimately, may not be achievable – but the claims do not lack enablement merely because they encompass that potential outcome.

The examiner has not adequately explained why the specification does not enable one skilled in the art to inhibit skin cancer in a mammal by administering sericin prophylactically. We therefore reverse the rejection of claims 5-12 under the first paragraph of 35 U.S.C. § 112.

Obviousness

The examiner rejected claims 5-12 under 35 U.S.C. § 103 as unpatentable over Yamada. Yamada teaches that many "diseases caused from daily life habit[s,]" including cancer, "may be at least partly caused [by] lipid peroxide produced and accumulated in vivo" and that antioxidants and tyrosinase inhibitors can be used "to solve such problems" (Yamada, column 1, lines 17, 23-24 and 64-65). Yamada describes "a composition . . . which comprises as an active ingredient a sufficient amount of sericin[, or its hydrolyzate,] to exert an antioxidizing ability and an inhibiting action on tyrosinase activity" (id., column 3, lines 36-40) which may be used in the "form of cosmetics or medicines for external use" (id., column 4, line 38) or "may be orally administered as medicines" (id., lines 48-49). According to Yamada, "a sufficient

amount" of sericin or its hydrolyzate for oral administration is about 10 mg to 100 g/day (in formulations comprising about 0.1-50% sericin by weight), while formulations of 0.1-50% sericin by weight are appropriate for external use (id., lines 29-30 and 48-51).

According to appellants (e.g., Specification, page 1), sericin is effective in inhibiting skin cancer prophylactically, and the claimed invention is directed to preventative use of sericin in mammals in need of treatment for inhibition of skin cancer. In other words, the claims encompass administering sericin to healthy mammals in an amount effective to inhibit skin cancer. The specification indicates that sericin formulations of 0.1-50% by weight produce "adequate effects" when ingested (id., page 4), and that external administration of formulations comprising 2.5% and 5% sericin by weight inhibits the development of skin cancer (id., pages 6-7). The examiner points out that these amounts and routes of administration appear to coincide with those described by Yamada (Answer, page 9).

We find no error in the examiner's conclusion that it would have been obvious for one skilled in the art to have administered sericin, "a known antioxidant, to inhibit a skin cancer" in a mammal in need thereof, inasmuch as Yamada teaches that "cancer may be at least partly caused from [accumulated] lipid peroxide . . . and that antioxidants have been used to solve such problems and further that sericin is a strong antioxidant" (Answer, page 7).

Appellants concede that Yamada teaches "that sericin can be used to counter the ill effects of lipid peroxides, which effects can cause cancer," but argue that "[s]kin cancer is a very particular type of cancer for which specific therapies are widely published . . . [c]onsequently, documents that mention cancer generally" are of little relevance to skin cancer (Brief, page 11). Appellants argue that "[t]he mere suggestion

of the use of sericin as a cancer preventative agent due to its antioxidant properties does not suggest to a person skilled in the particular art of treating patients in need of inhibiting skin cancer that sericin would be beneficial for such a relatively narrow group of patients" (id.), and the claimed invention is patentable as "a new use of a known . . . composition of matter" (id.).

We disagree. At best, the present claims articulate a newly recognized or newly discovered benefit of an old process. It is well established that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. See In re Woodruff, 919 F.2d 1575, 1577, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Woodruff's claims to a "process for inhibiting the growth of fungi on fresh leafy and head vegetables comprising maintaining said . . . vegetables in [a] modified gaseous atmosphere" at low temperature (id. at 1575, 16 USPQ2d at 1934) were held to be unpatentable over a patent describing a method of storing fresh leafy and head vegetables in a modified gaseous atmosphere at low temperature in order to retard respiratory, bacterial, and enzymatic deterioration (id. at 1577, 16 USPQ2d at 1935). The court recognized that "Woodruff may have been the first to recognize the fungal-inhibiting benefit of the method[,]" but found that "[t]he generic purpose of the method disclosed in [the patent] is to prevent the deterioration of fresh vegetables, which certainly encompasses the specific benefit disclosed by Woodruff" (id. at 1577, 16 USPQ2d at 1936).

Here, Yamada explicitly suggests that accumulation of lipid peroxide is an underlying cause of cancer, and that sericin is an antioxidant effective in preventing accumulation of lipid peroxide. We agree with the examiner that this would have suggested prophylactic administration of sericin to inhibit the development of cancer.

Moreover, the purpose of Yamada's method is to prevent accumulation of lipid peroxide, which Yamada teaches is an underlying cause of cancer in general, and this encompasses the specific benefit disclosed by appellants – prevention of skin cancer. In our view, it is of no moment whether one of ordinary skill in the art would have expected sericin to inhibit cancer generically, or skin cancer narrowly, and we do not agree that the present invention can be termed "a new use of a known composition."

In our opinion, Yamada's disclosure is sufficient to establish a prima facie case of unpatentability against the claimed invention, and the decision of the examiner is affirmed.

CONCLUSION

We have reversed the rejection of claims 5-12 under 35 U.S.C. § 112, first paragraph, but affirmed the rejection of claims 5-12 under 35 U.S.C. § 103.

AFFIRMED

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